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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER: O

1801/1223

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ART UNIT	PAPER NUMBER
1802	16

DATE MAILED: 12/23/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/7/97 & 10/6/97.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 22-79 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 22-79 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of the cancer antigens species in Paper No. 15 is acknowledged.

Claim Rejections - 35 U.S.C. § 112

2. Claims 29, 61, and 78-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 61 are vague and indefinite in reciting a trademark compound (Tween 20) in the claims. The composition of trademark compounds can be changed without changing their trademark name. This rejection can be obviated by inserting generic terminology in the claims to clearly define the trademark compound.

Claim 78 is vague and confusing as the function of the first antibody in not clear in relation to the second and third antibodies.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 22-27, 30-33, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Widder et al (EP 016,552).

See paper 9 for the teachings of Widder et al.

Claim Rejections - 35 U.S.C. § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 28-29 and 48-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder et al in view of Connelly et al (U.S. Patent 5,422,277).

The method of Widder et al differs from the instant invention in failing to teach the use of a mild detergent to treat the cells and failing to teach the use of an antibody to immobilize antibodies on the surface of the magnetic particles.

See paper 9 for the teachings of Connelly.

It would have been obvious to one of ordinary skill in the art to use detergents, such as Tween, as taught by Connelly et al in the method of Widder et al because the use of mild

detergents to treat cells is well known and conventional in the art for removing extraneous matter from the cells that may interfere with assays.

It would have been obvious to one of ordinary skill in the art to use antibodies to immobilize antibodies on the surface of the magnetic particles in the method of Widder et al because such method of immobilizing antibodies on the surface of a solid support, such as magnetic particles in conventional and well known in the art.

7. Claims 34-35, 37-45, and 66-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder et al in view of Kemmer et al and Holmes et al.

The method of Widder et al further differs from the instant invention in failing to teach the specific cells that are to be separated and detected recited in claims 34-35 and 37-45.

See paper 9 for the teachings of Kemmer et al and Holmes et al.

It would have been obvious to one of ordinary skill in the art to use the method of Widder et al to separate cells from a variety of cell samples, as taught by Kemmer et al and Holmes et al, because Kemmer et al and Holmes et al teach that it is advantageous to remove tumor cells from a mixed cell suspension using magnetic microbeads coated with either monoclonal antibodies or Protein A for the purpose of further studying the tumor cells or to purge a sample of tumor cells. The use of various monoclonal antibodies specific for antigens present on the cell surface is well known in the art and a skilled artisan would have had a reasonable expectation of success in

choosing an antibody that is specific for an antigen present on the surface of the cell population of interest.

8. Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder et al in view of Forrest et al (U.S. Patent 4,659,678).

The method of Widder et al differs from the instant invention in failing to teach the use of avidin and biotin and a test kit.

See paper number 9 for the teachings of Forrest et al.

It would have been obvious to one of ordinary skill in the art to a binding system such as avidin/biotin, as taught by Forrest et al, in the method of Widder et al because Forrest et al teach that avidin/biotin provides a very rapid and high binding affinity which offers the advantage of a more accurate and rapid assay.

It also would have been obvious to one of ordinary skill in the art to place the reagents required for performing the method of Widder et al, as modified by Forrest et al, in a test kit arrangement because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

9. Applicant's arguments with respect to claims 22-79 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027 or at e-mail address james.housel@uspto.gov. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

chin/cc
December 22, 1997

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800